REMARKS

This is in response to the Office Action dated 11/12/08.

Claims 1-7 and 9-11 were previously canceled, with claim 8 being the only claim pending in the present application. Claims directed to treatment of scarring are currently being prosecuted in related co-pending application 11/091,037.

§ 112, 1st Paragraph, Rejection

Claim 8 was rejected under 35 USC 112, 1st paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully submit, however, that claim 8 does fully comply with the written description requirement. Claim 8:

> 8. A method of visibly reducing a human skin wrinkle comprising:
> topically applying to the human skin wrinkle an IRM compound that is an agonist of TLR7, TLR8, or both TLR7 and TLR8 in an amount and for a period of time sufficient to visibly reduce the wrinkle; wherein the IRM compound is an imidazoquinoline amine, a tetrahydroimidazoquinoline amine, an imidazopyridine amine, a 1,2-bridged imidazoquinoline amine, a 6,7-fused cycloalkylimidazopyridine amine, an imidazonaphthyridine amine, a tetrahydroimidazonaphthyridine amine, an oxazoloquinoline amine, a thiazoloquinoline amine, an oxazolopyridine amine, a thiazolopyridine amine, an oxazolonaphthyridine amine, a thiazolonaphthyridine amine, or a combination thereof.

According to MPEP 2163 I.A., first sentence, "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." It is clear that the inventors had possession of the claimed invention as defined by claim 8. While the Office Action correctly notes that additional work would be required to practice the claimed invention for a given IRM compound class, that goes primarily to the question of enablement and not written description. Further, as to enablement, the amount of work necessary to practice the invention of claim 8 would not require "undue experimentation."

The compound classes listed in claim 8 (as originally filed) are also expressly described at page 2, line 30, to page 3, line 3, of the specification. Many examples within the TLR 7 and/or 8 agonist IRM compound classes listed in claim 8 are disclosed in the patent applications listed in the paragraph bridging pages 3-4 of the specification. One skilled in the art would readily understand that such compounds operate through a common TLR 7 and/or 8 mechanism

and how to formulate such compounds for topical administration. Examples of topical formulations can be found in disclosures of the patent documents referenced on page 7, last paragraph, of the specification. The disclosures of the patent documents referenced are all incorporated by reference in the present application (see page 18, lines 4-6). The present application disclosure provides clear direction to one skilled in the art as to how to practice the claimed invention—i.e., apply a topical preparation of one of the claimed IRM compounds--and is not merely a "hunting license."

Accordingly, it is requested that the rejection under 35 USC 112, 1st paragraph, be withdrawn.

§ 103 Rejection

Claim 8 was rejected under 35 USC § 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1). Applicants respectfully traverse.

Yu et al. is directed to the topical use of oligosaccharide aldonic acids for a very wide range of cosmetic and dermatologic purposes, including wrinkles. Yu et al. also discloses that various compounds may be combined with oligosaccharide aldonic acids. However, Yu et al. does *not* disclose or suggest that all of the compounds that may be combined with oligosaccharide aldonic acids are useful for all the same purposes as those taught for the oligosaccharide aldonic acids.

To the contrary, it is clear from the disclosure at column 12, lines 8-52 of Yu et al. that Yu et al. is actually disclosing to use oligosaccharide aldonic acid to amplify the effect of the other cosmetic or pharmaceutical agents. Imiquimod was a known antiviral pharmaceutical and Yu et al. expressly states that, "The cosmetic and pharmaceutical agents which may be actuated by oligosaccharide aldonic acids and related compounds include . . . antiviral agents" (underline added). Yu et al. thus does not imply that imiquimod works as an anti-wrinkle treatment, but that oligosaccharide aldonic acid would be useful for enhancing imiquimod's known use as an antiviral agent.

Yu et al. claims 10, 31, and 42 (cited in the Office Action) must be read in light of the corresponding disclosure, and it is thus clear that Yu et al. was not suggesting imiquimod as an

anti-wrinkle agent. Thus, while the Office Action acknowledges that Yu et al. does not specifically teach applying imiquimod to treat wrinkles, Applicants respectfully submit that Yu et al. does not even hint at any such use for imiquimod, but merely lists imiquimod because it was a known topical anti-viral agent.

Maibach et al. does not remedy the deficiencies of Yu et al. because Maibach et al. merely discloses that imiquimod is a treatment for warts – not wrinkles. It actually appears that paragraph 0092 of Maibach et al. may be an erroneous inclusion, since it appears to have no relevance to the rest of the disclosure and the following paragraph 0095 has the same heading "Active Ingredients" and address hyperpigmentation. In any case, one skilled in the art would certainly not read Maibach et al. as suggesting use of imiquimod for treating wrinkles where it is very clear that Maibach et al. is listing imiquimod as a wart treatment.

Third, even if one were to accept Yu et al. as suggesting imiquimod for treating some age-related dermatological disorders, and Maibach et al. as treating hyperpigmentation, the combination still would not have taught use of imiquimod to treat wrinkles per se.

Accordingly, it is submitted that the rejection of claim 8 under 35 USC § 103(a) should be withdrawn.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application is requested.

Respectfully submitted,

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